IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [46] 1:22-cv-00490-LMM [44] 1:22-cv-01583-LMM [54]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on Defendant's motion to exclude the opinions of Jimmy W. Mays, Ph.D., from evidence in support of the claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs").[1] Upon due consideration, the Court enters the following Order.

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

I. BACKGROUND

Paragard is an IUD that is implanted into a patient by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008. Cooper acquired the Paragard NDA from Teva on November 1, 2017.

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected to have a follow-up procedure to have the Paragard removed per the removal instructions on the label. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

Plaintiffs retained Dr. Mays, a polymer chemist and biomaterials expert, to assess whether Paragard has any properties or manufacturing issues that cause it to break more than other IUDs. Dkt. No. [56-5] at 12[2]; Deposition of Jimmy Mays, Ph.D. ("Mays Dep.") at 9-10. Dr. Mays opined that (1) the materials chosen and how the Paragard is manufactured cause oxidative degradation, weakening the Paragard; (2) the high levels of untreated barium sulfate incorporated into the T-shaped polyethylene base of the Paragard make it susceptible to breakage; (3) the Paragard manufacturers failed to comply with World Health Organization/United Nations Population Fund ("WHO/UNFPA") standards that would have resulted in significantly fewer breakages; (4) there were pervasive quality control issues in the manufacture of the Paragard, including that the Paragard manufacturers failed to address known problems with the Paragard after it went to market in 1981 and failed to carry out ongoing due diligence that is expected of a manufacturer; (5) the sharp right angle of the "T" design also caused the Paragard to break more frequently; and (6) safer alternative designs were available but were never implemented by the manufacturers. Dkt. No. [56-5] at 12.

Defendant seeks to exclude Dr. Mays' testimony and opinions under Rule 702 of the Federal Rules of Evidence. It argues that Dr. Mays' testimony and

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

opinions should be excluded because they are not scientifically reliable; because Dr. Mays seeks to testify about topics outside his knowledge, skill, experience, training, or education; and because he seeks to offer opinions outside the realm of any expert witness.

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (cleaned up). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes

the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: whether the theory or technique in question can be (and has been) tested; whether the theory or technique has been subjected to peer review and publication; the known or potential rate of error; and general acceptance of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's

research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotation marks omitted). "Quite the contrary, '[v]igorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (alteration in Quiet Tech.).

III. DISCUSSION

Dr. Mays is a nationally recognized scientist and Professor Emeritus at the University of Tennessee, with more than forty years of experience researching, teaching, and publishing on polymer chemistry, degradation, and biomaterials. See generally Dkt. No. [82-2] (Mays CV); Mays Dep. at 17. His work in this area includes development of novel bone cements, dental restorative resins, tissue engineering, drug delivery systems, surgical sealants, and polypropylene pelvic mesh. Mays CV; Mays Dep. at 10-11. He has authored hundreds of peer-reviewed papers, book chapters, and scientific presentations on polymers. Mays CV at 4-106. Dr. Mays has provided expert witness testimony in numerous lawsuits, especially those involving medical devices and polymer science, including

polymer properties and degradation, representing both plaintiffs and defendants. See, e.g., Mays Dep. at 17-19; Bayless v. Boston Sci. Corp., No. 21-14397, 2023 WL 1466607, at *2-3, 6 (11th Cir. Feb. 2, 2023); Redding v. Coloplast Corp., Case No. 6:19-cv-1857, 2022 WL 20829230, at *2-7 (M.D. Fla. Mar. 26, 2022); Boneta v. Am. Med. Sys., Case No. 20-CIV-60409, 2021 U.S. Dist. LEXIS 248575, at *14-15 (S.D. Fla. Sept. 27, 2021).

A. Need for Testing

A persistent argument throughout Defendant's motion to exclude Dr. Mays' opinions is that Dr. Mays did no independent testing on any Paragard. However, an expert need not perform new testing where his or her opinions are grounded in established science and informed by the expert's knowledge, experience, training, or education. United States v. Esformes, 60 F.4th 621, 637 (11th Cir. 2023); In re Seroquel Prods. Liab. Litig., Case No. 6:06-md-1769, 2009 U.S. Dist. LEXIS 115653, at 153-56 (M.D. Fla. June 23, 2009) (finding expert's experience and literature search a reliable means of establishing causation). A court, of course, cannot simply take an expert's word at face value: the expert must explain the basis for his opinion and explain why it supplies "good grounds, based on what is known." United States v. Frazier, 387 F.3d 1244, 1261-65 (11th Cir. 2004) (cleaned up) (explaining that when evaluating a scientific opinion under Rule 702, the opinion must have a scientific foundation). Yet a court cannot look too narrowly at each individual consideration—so long as

the expert's overall methodology is sound, his or her opinion is admissible. Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1233 (9th Cir. 2017) (finding error where district court "overemphasized [that] experts did not develop their opinions based on independent research" over evidence of the expert's experience and reliance on literature and studies).

Thus, Dr. Mays' opinions are not excludable simply because he did not undertake independent testing of a Paragard. Rather, each challenged opinion will be reviewed based on Dr. Mays' experience and his overall methodology, his explanations, and the reliability of his sources.

B. Challenges to Opinions for Lack of Reliable Methods or Reasoning

1. Opinions on Oxidative Degradation

Dr. Mays found that the low-density polyethylene ("LDPE") used in the Paragard T-frame is unstabilized and therefore inherently susceptible to oxidation; that contact with copper catalyzes the body's inflammatory response, generating reactive oxygen species that accelerate oxidation of the Paragard's T-frame; and that oxidation causes the LDPE to stiffen and become brittle, increasing the likelihood of fracture in the body and during removal. Dkt. No. [56-5] at 17-38. Defendant argues that these opinions should be excluded because Dr. Mays assumed his conclusion, did not conduct independent testing, and selectively cited sources generally discussing polymer degradation while ignoring contrary evidence.

As discussed above, Dr. Mays was not required to perform testing on a finished Paragard or its raw material, as testing is not per se required. See supra Part III.A. While Defendant argues that Dr. Mays' lack of testing is all the more glaring because his hypothesis is testable, as allegedly demonstrated by the mechanical testing performed by Defendant's materials-science expert, Dr. Stephanie Benight, Dr. Benight's testing is only on a new Paragard. This is inapposite to Dr. Mays' opinion, as oxidation of a new Paragard is not the point of Dr. Mays' opinion. Dr. Mays opines that the polymers begin oxidizing immediately, but he does not contend that it would be apparent on a new device. It also is not clear how Dr. Mays would perform an independent test, as there were no explanted Paragards available for analysis, and according to Dr. Benight, oxidation is not evident on a new product. Dkt. No. [56-6] at 11.

The Court agrees with Plaintiffs that Dr. Mays can instead use his experience with chemistry and polymers to talk about how these materials degrade in the conditions that they are in. Dr. Mays is qualified to offer opinions on oxidative degradation due to his advanced education in polymer science, decades of research and teaching focused on polyolefins (including polyethylene), direct experience with polymer characterization and degradation, significant scholarly and industrial impact, recognized expertise by courts and peers, and his application of rigorous, literature-supported scientific methodology. His qualifications are further reinforced by his hands-on experience with relevant

materials and his ability to synthesize scientific, regulatory, and company information to form reliable conclusions.

Dr. Mays' opinion is, in effect, using polymer science to explain how the materials used in the Paragard T-form degrade. His opinions on oxidative degradation are grounded in a comprehensive review of peer-reviewed scientific studies, authoritative textbooks, international standards, and regulatory documents. He also educated himself on the specifics of the Paragard by reviewing a range of internal company documents relating to Paragard, including the New Drug Application ("NDA"), documents regarding the raw material specifications, materials sourcing, materials and manufacturing processes, testing protocols and records, audits, internal adverse event data, and communications with the FDA regarding adverse events. These sources collectively document the mechanisms, evidence, and consequences of oxidative degradation in polyethylene, both inside and outside the body, and specifically as it relates to medical devices such as the Paragard IUD. Even Dr. Benight seems to find Dr. Mays' methodology suitable. See Deposition of Stephanie Benight, Ph.D. ("Benight Dep.") at 59 ("Q: So you would agree with me that looking at published literature with respect to the properties of material would be part of an acceptable scientific method in order to reach your conclusions in this case? A: Yes.").

The Court also finds Defendant's specific critiques of Dr. Mays' research to be mostly unpersuasive. It is true, as Defendant points out, that certain courts have found that Dr. Mays overreached the limits set by the authors in Anderson (2008) when he cited the study to support an opinion that polyethylene is constantly attacked by oxidative agents as long as it remains inside the body. See Arevalo v. Coloplast Corp., No. 3:19cv3577, 2020 WL 3958505, at *6 (N.D. Fla. July 7, 2020) (criticizing Dr. Mays' reliance on J. Anderson et al., Foreign Body Reaction to Biomaterials, 20 Seminars in Immunology 23, 86-100 (2008)); Cantrell v. Coloplast Corp., No. 20-cv-0672, 2022 WL 2806390, at *4 (D. Minn. July 18, 2022) (same). Review of Dr. Mays' report reveals, however, that he did not rely on that study alone for any of his degradation opinions.

Defendant also faults Dr. Mays for overreaching by relying on articles like Fernandez (2021) and Latack (2023) to support an opinion that Paragard has a higher rate of breakage than other copper IUDs. Plaintiffs state, however, that the papers are not used to calculate Paragard's breakage rate and instead are cited only for their value in corroborating that multiple independent researchers have observed fracture patterns consistent with the oxidative degradation Dr. Mays describes—that Paragard's materials and design make it prone to oxidation-induced breakage, particularly after prolonged use. Based on this representation,

he can refer to the Fernandez and Latack articles for their corroborating value, but he will not testify about Paragard's relative breakage rate.

Defendant also argues that Dr. Mays overreaches in his citations to Allara (1976) and Sack (1984) to support his assertion that copper is known to serve as a catalyst for oxidative degradation of polyethylene. It contends that because the studies involved heating the polyethylene in contact with the copper to greater than 90 degrees Celsius for long durations, the study conditions are too far afield from the facts of this case to be useful. The Court disagrees based on the Paragard sterilization protocol, which, as described, exposes polyethylene in contact with copper for a prolonged period of time. The Court therefore finds no basis for excluding testimony on this basis.

Finally, Defendant faults Dr. Mays for not addressing certain opinions about the reactivity of "pure" copper offered by their expert Dr. Benight. However, "an expert is not required to address all alternative theories, nor would an expert's failure to do so be a sufficient basis for exclusion where the court is the factfinder." Waters v. AIG Claims, Inc., 608 F. Supp. 3d 1120, 1135 (M.D. Ala. June 22, 2022) (citing Fuller v. SunTrust Banks, Inc., No. 1:11-CV-784, 2019 WL 5448206, at *20 (N.D. Ga. Oct. 3, 2019)). Additionally, as Defendant concedes that the copper on Paragard is 99.99% pure, it is unclear whether the properties of "pure" copper apply. The Court therefore finds no basis for exclusion in this argument.

2. Opinions on Barium Sulfate

Dr. Mays opines that the high barium sulfate content in the polymer further reduces toughness and, when poorly dispersed, creates stress points that act as crack initiators. Dkt. No. [56-5] at 42-45. The Court also finds that this opinion is admissible.

Again, Dr. Mays does not need to conduct independent testing and can instead rely on work of others. And while Defendant faults Dr. Mays for misplaced reliance on the Nazar study to support his conclusion that the agglomeration of barium sulfate causes Paragard breakage, Dr. Mays cites several other studies for the same point. See, e.g., Dkt. No. [56-5] at 44, 62-63 (citing Chen (2010); Makita (2008); Verbeke (2010); Shearwood-Porter (2012); Artola (2003)). Additionally, Dr. Mays has direct experience with barium sulfate as a filler in polymer composites. Dkt. No. [56-5] at 5.

As such, the Court does not find grounds for excluding Dr. Mays' opinions regarding the effects of high barium sulfate concentration in the Paragard T-form.

3. Opinions on Design and Manufacturing Processes

Dr. Mays also opines that the materials and manufacturing process of Paragard contributes to the rate of breakage of Paragard. More specifically, he opines that the T-shaped Paragard design, the selection of LDPE formulations, repeated heating during manufacture, copper exposure during sterilization, faulty

quality control protocols, and long shelf life of Paragard contribute to its propensity to break. Dkt. No. [56-5] at 45-54, 85-87.

The Court need not address the opinions on the T-shape design and manufacturing defects because they are no longer in the case. See Dkt. No. [137] at 17-18 & n.3. The only reason the opinions on the T-shape, faulty storage protocols, or other manufacturing defects are relevant is to the extent that Dr. Mays opines that the design is even more problematic because of the T-shape or the way the products are stored.

To the extent that those opinions are relevant to the Paragard design, the research grounding those opinions appears to be sound. In his report, Dr. Mays goes through the timeline and the different formulations of LDPE using internal company documents and his knowledge of polymers from his experience as an industrial research chemist at Hercules Inc. and his forty years in polymer science. He points to specific internal company documents indicating that Defendant switched from Dupont 2005 to Dupont 20 in 2007 and that storage areas were not consistently controlled for temperature and sunlight exposure. Dkt. No. [56-5] at 45-52. He also explains the differences in tensile strength, flexibility, and molding temperature between Dupont 2005 to Dupont 20 in 2007. Id. at 49. He cites peer-reviewed studies in discussing the effect of the right angle in the T-shape as a stress concentrator. Id. at 86. And as discussed above, Dr. Mays has demonstrated his knowledge of the way that polymers oxygenate

and may be compromised by high concentrations of barium sulfate, and he has supported those opinions with scientific studies and data. See supra Part III.B.1., 2.

Finally, the Court is not persuaded by Defendant's allegation that Dr. Mays impermissibly ignored an FDA review of adverse event reports that concluded that there were no identified factors contributing to the increased number of breakage reports observed at some timepoints. As Dr. Mays pointed out in his deposition, the FDA review went on to state, "However, there does appear to be a lack of robust testing on the limits of the design of the product, most likely due to the fact that the product was developed over 40 years ago when such robust testing was not a regulatory requirement." Mays Dep. at 261. This qualifier makes clear that the FDA did not rule out design or manufacturing issues. As such, the Court is not persuaded that the FDA review detracts from Dr. Mays' opinions, much less renders them inadmissible.

Accordingly, the Court concludes that Dr. Mays may testify about the Paragard manufacturing processes so far as they bear on the effect of choosing Dupont 20 over Dupont 2005 or including the high concentration of barium sulfate, the only two design-defect claims remaining in the case.

C. Dr. Mays is not qualified to offer certain opinions

1. Dr. Mays is not qualified to testify about whether Defendants complied with product quality standards

Dr. Mays opines that Defendant should have tested the Paragard under WHO/UNFPA specifications for tensile strength, for barium sulfate particle size and distribution, and for breaking force of the molded and sterilized T-form. Dkt. No. [56-5] at 64-68. He also contends that Defendant should have routinely tested the polyethylene in the Paragard T-form for oxidative degradation using infrared spectroscopy, molecular weight measurements, mechanical testing, or a combination of these tests. Id. at 69.

The Court does not find these opinions problematic to the extent that Dr. Mays is saying that Defendant should conduct more testing on their products to figure out why they are breaking and seeing how they are performing. Dr. Mays explains how infrared spectroscopy, molecular weight measurements, and mechanical testing measure degradation and structural weaknesses. And while he relies on WHO/UNFPA standards, these are acceptable as examples of what testing could be done from an engineering perspective. It can also show testing that others do. If there is concern as to the jury being confused as to whether this is a legal requirement, the Court can give a limiting instruction on this, if necessary.

2. Dr. Mays is not qualified to testify about purportedly safer alternative product designs

Dr. Mays suggest that a "Nova-T" shaped IUD or an IUD constructed with a softer T-shape, a different polymer, and use of x-rays or microscopy to assure adequate dispersion of barium sulfate would result in an IUD that is safer than Paragard in its current design. The claims for design defect are preempted aside from the choice to use Dupont 20 rather than Dupont 2005 and the incorporation of up to 24% barium sulfate in the Paragard base materials. Dr. Mays' testimony on reasonable alternative design is therefore limited to his understanding of polymer strength within those parameters.

3. Dr. Mays is not qualified to testify about medical causation

Next, Defendant seeks to exclude Dr. Mays' testimony suggesting that the "foreign body response" to Paragard's copper and any shedding polymer particles may lead to systemic autoimmune or autoinflammatory conditions in women. Dr. Mays is not a medical doctor, and Plaintiffs agree that he will not testify about medical causation. Dkt. No. [83-1] at 36.

Instead, Dr. Mays will testify how the conditions in the body can impact the polymers. Thus, he can testify that the Paragard T-form may degrade in the body due to the well-recognized "foreign body response" and that the properties of the Paragard may change as a result, but he may not testify as to the clinical implications of that degradation. For example, he may not testify that

degradation of the Paragard T-form could cause pain or bleeding or provoke an autoimmune disease, nor may he offer opinions on any other medical diagnoses.

D. Dr. Mays offers opinions that are otherwise improper

1. Dr. Mays cannot suggest Defendants committed fraud on the FDA

There is no claim for fraud on the FDA, but in stating the factual basis for those of his opinions where it is relevant that the reports to the FDA were complete and correct, Dr. Mays can say that the information provided to the FDA was incomplete or wrong or false. See In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2187, 2018 WL 4212409, at *3 (S.D.W.Va. Sept. 4, 2018) ("[A]n expert may testify as to a review of internal corporate documents . . . for the purpose of explaining the basis for his or her opinions."). Defendant has made clear that it plans to introduce argument that the FDA did not order it to change the Paragard. Thus, Plaintiffs may introduce evidence that the FDA did not have the correct information. Dr. Mays is, however, limited from implying that incomplete, wrong, or false reports to the FDA form the basis for a claim.

2. Dr. Mays cannot testify as to a defendant's state of mind

Defendant argues that Dr. Mays goes beyond the permissible bounds of expert testimony to comment on Defendant's knowledge, state of mind, or corporate conduct. Plaintiffs agree to limit Dr. Mays' testimony to identify what Defendant knew or should have known, as reflected in their own data, and how

that knowledge aligns with the objective polymer-science evidence. He will not and is not permitted to speculate about motives.

3. Dr. Mays cannot testify as to legal conclusions

Defendant takes issue with Dr. Mays' conclusion in his report that Paragard is "inherently defective and unreasonably dangerous." However, "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). Rather, "an expert may testify as to his opinion on an ultimate issue of fact provided that he does not merely tell the jury what result to reach or testify to the legal implications of conduct." United States v. Graham, 123 F.4th 1197, 1262 (11th Cir. 2024) (quoting United States v. Grzybowicz, 747 F.3d 1296, 1310 (11th Cir. 2014) (cleaned up)).

Thus, Dr. Mays can offer expert opinions that there are design defects, but he must make clear that the opinions are based on his expert judgment and are not a legal conclusion. If necessary, the Court can give a limiting instruction on this.

IV. CONCLUSION

Defendant's motion to exclude the opinions of Jimmy W. Mays, Ph.D., from evidence in the bellwether cases is **GRANTED IN PART AND DENIED IN PART**, as set out above.

IT IS SO ORDERED this 5th day of January, 2026.

Leigh Martin May
Chief United States District Judge